SHELBY COUNTY HEALTH DEPARTMENT

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Public Health
Prevent. Promote. Protect.

May 9, 2017

Mr. Jodie L. Jefferson
Plant Manager
Sterilization Services of Tennessee
2396 Florida St
Memphis, Tennessee 38109

RE: 2017 Annual Compliance Inspection

Dear Mr. Jefferson:

Enclosed please find a copy of the report of the Annual Compliance Inspection performed at the Sterilization Services of Tennessee facility located at 2396 Florida St. on May 04, 2017. The Department would like to thank Mr. Calvin Spencer for his assistance with this inspection.

Should you have any questions regarding this report please call me at (901) 222 -9582.

Sincerely,

Billy C. Smith
Major Sources Supervisor
POLLUTION CONTROL SECTION

Enclosure

cc: Source Files - #00477
Branch Correspondence Files
Inspection Book

IN out T-
00477033

PLANT INSPECTION REPORT

COMPANY:	Sterilization Services of Tennessee
SOURCE #:	00477
CLASSIFICATION:	Synthetic Minor
PERMIT EXPIRATION DATE:	03/16/2020
ADDRESS:	2396 Florida St, Memphis, TN 38109
PHONE:	(901) 947-2217
SOURCE CONTACT:	Jodie L. Jefferson, Plant Manager
PURPOSE OF INSPECTION:	Annual Compliance Inspection
PRIOR NOTICE:	YES
FACILITY DESCRIPTION:	Sterilization of Customer Equipment
NAICS CODE:	561910
ENVIRONMENTAL CONDITIONS:	Sky: Light Rain and Overcast Temperature: 52 ^{O}F Winds: NW 9-15 mph, gust to 23 mph
INSPECTOR:	Bill Smith
DATE OF INSPECTION:	May 04, 2017
TIME:	~ 1:00 PM
COMPLIANCE STATUS:	IN

Existing Permits:

Number	Equipment Description	Issued	Expires
00477-02P	Three Ethylene Oxide Sterilizer, (Units 0101, 0102, and 0103), two aeration rooms and associated air pollution control equipment (acid –water scrubber and catalytic oxidizer)	03/16/2015	03/16/2020

Process Descriptions/ Conditions Found:

The facility currently consists of three sterilizers (one sterilizer is not working) and one aeration room. At the present time, all three sterilizers are connected to a common acid-water scrubber (Damas packed tower scrubber) with a minimum control efficiency of 99 percent. The sterilization chamber exhaust vents and aeration room vents are routed to the thermal oxidizer for control (the minimum control efficiency of the oxidizer is required to be 99 percent). Sterilization Room 1 is not operating.

New medical products are transferred from the unloading/storage area and loaded into one of the three sterilizers, which are identified as 0101, 0102, and 0103. To sterilizers were operating during the inspection. Ethylene oxide gas is used as the sterilant. The sterilizing cycle includes the following stages: 1) exposure of medical products to sterilant under pressure; 2) sterilant removal, including nitrogen washes and air washes; 3) unloading of sterilized products; and 4) aeration to facilitate off-gassing of ethylene oxide retained in the sterilized products. A computerized system is used to monitor and control the process parameters like pressure, temperature, EtO concentration, and other parameters for the sterilization chambers.

Ethylene oxide emitted from the sterilization chamber vents during the sterilant removal stage, including the vacuum pump discharge during nitrogen and/or air washes, are routed to the acid-water scrubber for emission control. Emissions from the sterilization chamber exhaust vents (~ 2.5% from the unloading of sterilized products) are routed to the thermal oxidizer for control. The natural gas fired oxidizer consists of two packed beds filled with catalysts. The oxidizer temperature, flame arrestor temperature, pressure, catalyst inlet and outlet temperatures, and other parameters are monitored. The oxidizer was running during the inspection.

The acid-water scrubber consists of three separate tanks, (two can be used at any one time, one is used for backup), each equipped with a liquor tank level indicator. When the maximum liquor tank level of 60 inches is reached, the content of the tank is vented to the waste tank. The spent scrubbing liquid is discharged to a holding tank and subsequently treated (e.g., neutralized) prior to being loaded into a tank truck and transferred offsite for reuse in other processes. A prescribed mixture of sulfuric acid and water is added to the scrubber and the operation of the scrubber is resumed. The scrubber appeared to be in good condition and working properly during the inspection.

The product absorbs/adsorbs approximately 2.5% of the EtO sterilant, which is subsequently released in the aeration room. The products typically spend a minimum of 24 hours and a maximum of 72 hours in the aeration room. Emissions from the aeration room vent are routed to the thermal oxidizer for control.

The source originally had two aeration rooms and the thermal oxidizer had four catalyst beds. Because of reduced throughput, the source took one of the aeration rooms out of service and removed from service two catalyst beds in the thermal oxidizer A stack test was conducted on July 16, 2015 to demonstrate compliance with the requirements of 40 CFR Part 63 Subpart O.

Depending on the rate of sterilant removal from a particular chamber, one or more chambers can be vented to the scrubber at one time, i.e., the sterilant removal time may be increased if two chambers are being vented instead of one.

Emission Points:

- Sterilization chamber vents - scrubber exhaust stack: Ethylene Oxide (EtO).
- Unloading of sterilized products from sterilization chambers - sterilization chamber exhaust vents: EtO
- Aeration rooms - aeration room vents: EtO.

Emission Controls:

- Sterilization chamber vents - acid-water scrubber.
- Sterilization chamber exhaust vents and aeration room vents – thermal oxidizer.

PERMIT CONDITIONS: (Selected for the Inspection)

1. The maximum ethylene oxide emissions from all emission sources at this facility shall not exceed 0.36 pounds per hour (24-hour average) and 1.59 tons per consecutive 12-month rolling period.

Review: Emissions for 2016 Ethylene Oxide were 0.94 tons.

2. The maximum ethylene oxide usage rate at this facility shall not exceed 36.25 lbs/hr (24-hour average) and 158.78 tons per consecutive 12-month rolling period.

Review: 2016 usage for Ethylene Oxide 44.58 tons.

3. The facility owner or operator shall limit emissions as follows:

Emissions Tons Per Year	**PM**	**SO2**	**NOx**	**CO**	**VOCs**	**HAPs**	**HAPs**
Process Description						Single	Combined
Catalytic Oxidizer *(1)(2)*	0.12	0.01	1.55	1.293	0.09	0.028	0.029
Ethylene Oxide (EtO)						1.59	1.59
Total	0.12	0.01	1.55	1.293	0.09	1.618	1.619

(1) Burning natural gas only.
(2) Values estimated based on fuel usage. Facility failed to submit these values to the Department.

4. The annual natural gas usage for the catalytic oxidizer shall be limited to 30.91 million cubic feet per consecutive 12-month rolling period.

Review: Records of gas usage are kept at the corporate office due to central billing. Records indicate 9,665,200 cubic feet of natural gas was used from January to December 2016.

5. The facility owner or operator is placed on notice that condition numbers 1-2 of this permit contain limitations that allow the owner/operator to opt-out of the major source operating permit program requirements specified in City of Memphis Code Section 16-77, Reference 1200-3-9-.02(11). Failure to abide by these limits will not only subject the owner/operator to enforcement action by the Department, but it may also result in the imposition of Federal enforcement action by the EPA and the loss of Federal recognition as a conditional minor source.

6. Emissions of ethylene oxide from all sterilization chamber vents at this facility shall be routed to the acid-water scrubber. The acid-water scrubber shall operate at a minimum ethylene oxide emission reduction efficiency of 99 percent during sterilization operation.

7. Emissions of ethylene oxide from the aeration room vents at this facility shall be routed to the catalytic oxidizer. The catalytic oxidizer shall operate at a minimum ethylene oxide emission reduction efficiency of 99 percent.

8. Permit condition not listed.

9. The maximum liquor tank level shall not exceed 60 inches.

   Review: Several logs were reviewed and all reads were below 60 inches.

10. *Permit condition not listed.*

11. *Permit condition not listed.*

12. The oxidation temperature shall not be less than 240^{O}F. [source request]

    Review: The Chart recorder was observed and the temperature was 280.9^{O}F at the time of the inspection. The chart indicated temperatures had been operating as required.

13. *Permit condition not listed.*

14. The following work practice shall be complied with by the owner or operator regarding the catalytic oxidizer:

    a. Every 5 years, beginning 5 years after the initial compliance test, replace the catalyst bed with new catalyst material. (Source Request)

    Note: The most recent stack test was performed July 16, 2015. The emission point was observed during the inspection. No visible emissions were observed.

15. *Permit condition not listed.*

16. Preventative and maintenance records shall be kept on all air pollution control equipment for a period of at least five (5) years and made available to this Department upon request.

    Review: These were being kept.

Conclusion:

Based on the review of record keeping provided by facility representatives and visual observations made during the physical site inspection, the Sterilization Services facility demonstrates compliance with their operating permit.